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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,644	07/21/2003	Gianni Plicchi	P07202US01/DEJ	4541
881	7590	08/24/2006	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314				KOHARSKI, CHRISTOPHER
ART UNIT		PAPER NUMBER		
				3763

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/622,644	PLICCHI ET AL.
	Examiner Christopher D. Koharski	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03 July 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-39 is/are pending in the application.  
 4a) Of the above claim(s) 2,4,8-12,14,17-21,23-29 and 32-35 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,3,5-7,13,15,16,22,30,31 and 36-39 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Claims 2, 4, 8-12, 14, 17-21, 23-29 and 32-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/3/2006.

Currently claims 1, 3, 5-7, 13, 15-16, 22, 30-31 and 36-39 are pending for examination in this application.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Faxon et al. (5,464,395). Faxon et al. discloses a catheter for delivering therapeutic agents to a tissue.

Regarding claims 1 and 30-31, Faxon et al. discloses a catheter with a hollow catheter body with a needle system on its terminal end with at least two lumens that correspond with terminal end needles with lateral discharge openings (Figures 1 and 11).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 is rejected under 35 U.S.C 103(a) as being unpatentable over Faxon et al. in view of Haim et al. (6,309,370). Faxon et al. meets the claim limitations as described above except a helical needle.

However, Haim et al. teaches an intracardiac drug delivery system.

Regarding claim 3, Haim et al. teaches a catheter system with a helical needle (Figure 1C).

At the time of the invention, it would have been obvious to add the helical needle of Haim et al. to the system of Faxon et al. in order to better anchor and achieve an effective surgical intervention. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art

would have combined the teachings in the references in light of the disclosure of Haim et al.

***Claim Rejections - 35 USC § 103***

Claims 6-7 are rejected under 35 U.S.C 103(a) as being unpatentable over Faxon et al. in view of Haim et al. in further view of Mahurkar (4,134,402). The modified Faxon et al. meets the claim limitations as described above except needles of different lengths.

However, Mahurkar teaches double lumen hemodialysis catheter.

Regarding claims 6-7, Mahurkar teaches a needle catheter with different length lumens in a terminal needle assembly (Figure 1).

At the time of the invention, it would have been obvious to incorporate the different length needles of Mahurkar to the system of Faxon et al. in order to allow for different injection profiles. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Mahurkar.

***Claim Rejections - 35 USC § 103***

Claims 14-16 are rejected under 35 U.S.C 103(a) as being unpatentable over Faxon et al. in view of Ryan (6,280,441). Faxon et al. meets the claim limitations as described above except for the central needle with a helical needle concentrically arranged.

However, Ryan teaches an apparatus for tissue treatment.

Regarding claims 14-16, Ryan teaches a straight and helical needle system that contains a straight needle aligned with the axis of the catheter and a helical needle arranged concentrically around the central needle (Figures 2 and 12).

At the time of the invention, it would have been obvious to the needle combination of Ryan to the system of Faxon et al. because the needle combination allows for terminal needle end stability. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Ryan.

#### ***Claim Rejections - 35 USC § 103***

Claim 22 is rejected under 35 U.S.C 103(a) as being unpatentable over Faxon et al. in view of Chien et al. (5,891,114). Faxon et al. meets the claim limitations as described above except a meshwork braided catheter support structure.

However, Chien et al. teaches a high performance braided catheter.

Regarding claim 22, Chien et al. teaches a catheter with a braided meshwork catheter support (Figures 1 and 2).

At the time of the invention, it would have been obvious to incorporate the meshwork of Chien et al. with the system of Faxon et al. because the meshwork support increase catheter tracking and aids in catheter placement. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Chien et al.

***Claim Rejections - 35 USC § 103***

Claims 36-39 are rejected under 35 U.S.C 103(a) as being unpatentable over Faxon et al. in view of Ryan. The modified Faxon et al. meets the claim limitations as described above except the specific needle and catheter measurements.

Regarding claims 36-39, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the dimensions of the catheter body and needles claimed, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

8/10/2008

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